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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/524,666	03/13/2000	John G. Aceti	SMI-13459pA	6745
21005	7590	02/23/2005	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133				DABNEY, PHYLESHA LARVINIA
ART UNIT		PAPER NUMBER		
		2643		

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	09/524,666	Applicant(s)	ACETI ET AL.
Examiner	Phylesha L Dabney	Art Unit	2643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 August 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 13,15,23,24,26,40,43,45,49 and 55-57 is/are withdrawn from consideration.
- 5) Claim(s) 46,48 and 50-54 is/are allowed.
- 6) Claim(s) 1-12,14,16-22,25,27-39,41,42,44,47 and 58-63 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/18/04.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

DETAILED ACTION

This action is in response to the amendments submitted on 13 August 2004 in which claims 1-12, 14, 16-22, 25-39, 41-42, 44, 46-48, 50-54, 58-63 are pending.

Claim Objections

1. Claim 35 is objected to because of the following informalities: the claim states that there is "the earmold". This limitation wasn't previously recited. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 11-12, 14, and 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by **Voroba** (U.S. Patent No. 4,870,688).

Regarding claims 11, and 17-19, Voroba discloses a modular hearing aid comprising: a base unit (99, 100), an earmold (30) comprising a compliant material and a retention mechanism (20,40,50,52), a receiver (70) and a module (90,101; col. 7 lines 51-68, col. 10 lines 60-64) comprising a shell (72) and electronics (70; 60, 90).

Regarding claims 12 and 14, Voroba discloses the earmold comprises a battery (80) removable attached to the earmold.

Regarding claim 16, Voroba discloses the module (90, 101) comprises a microphone (90).

3. Claims 44 and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Yoest et al (U.S. Patent No. 6,097,825).

Regarding claims 44 and 47, Yoest discloses a hearing aid comprising a base unit (50, 70, 86, 90, 120) and a potting material (92a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voroba et al (U.S. Patent No. 4,870,688).

Regarding claim 1, Voroba, or Weeks teaches a in the ear hearing aid comprising a base unit (99-100, Voroba), and an earmold (30) being able to be removably attached to the base unit comprising a compliant material; the earmold adapted to contain a hearing aid component (non-electrical component, 20) non-removably integrated within the earmold (col. 8 lines 9-13, col. 9 lines 1-4). Neither Voroba nor Weeks specifically teaches the earmold having a shorter life than the base unit. However, it is known in the art to be able to replace the earmold portion within the life expectancy of the aid if the structure becomes compromised, i.e. brittle and torn, and improve comfort and hygienic concerns for the user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to change the earmold of Voroba or Weeks within the life expectancy of the aid for improved comfort and hygienic concerns.

Regarding claim 8, the combination of Voroba or Weeks teaches the earmold forms an earmold tip (see figures).

Regarding claim 9, the combination of Voroba or Weeks teaches the earmold forms an earmold sleeve.

Regarding claim 10, the combination of Voroba or Weeks teaches the earmold forms an earmold tip and sleeve.

5. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Diethelm** (U.S. Patent No. 3,852,540), in view of **Voroba et al** (U.S. Patent No. 4,870,688).

Regarding claims 1-2, 6, and 8-10, Diethelm teaches a base unit (2), an earmold (1, 3) removable attached to the base unit, a retention mechanism (col. 3 lines 13-34), and the earmold

comprising a battery (7, 8). Diethelm does not teach the type of material used for the earmold; however, it is known in the art, as evidenced by Voroba (30), to use soft, malleable, compliant material for the earmold to facilitate comfort to the user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the shell of Diethelm from a soft, malleable, compliant material to facilitate comfort to the user. Neither Diethelm nor Voroba teaches the earmold having a shorter life than the base unit. However, it is known in the art to be able to replace the earmold portion within the life expectancy of the aid if the structure becomes compromised, i.e. brittle and torn, and improve comfort and hygienic concerns for the user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to change the earmold of Diethelm in view of Voroba within the life expectancy of the aid for improved comfort and hygienic concerns.

Regarding claim 3, the combination of Diethelm and Voroba teaches a shell integrated with the earmold (1, 3) and housing the battery (8) and a receiver (5).

Regarding claim 4, the combination of Diethelm and Voroba teaches a base unit (2), an earmold (1, 3) removable attached to the base unit, a retention mechanism (col. 3 lines 13-34), and the earmold comprising a battery (7, 8) and receiver (5). Diethelm does not teach the type of material used for the earmold; however, it is known in the art, as evidenced by Voroba (30), to use soft, malleable, compliant material for the earmold to facilitate comfort to the user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the shell of Diethelm from a soft, malleable, compliant material to facilitate comfort to the user.

Regarding claims 5 and 7, the combination of Diethelm and Voroba teaches a shell integrated with the earmold (1, 3) and housing the battery (8) and a receiver (5).

6. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Voroba et al** (U.S. Patent No. 4,870,688); in view of **Schroder** (U.S. Patent No. 4,736,430).

Regarding claim 22, Voroba teaches replacing a base unit of a hearing aid comprising the steps: providing a modular hearing aid (10) having a base unit (200) an earmold (30) and a module component (70); releasing a securing mechanism (50, 52, 244, 246, 248); removing the base unit (200); discarding the base unit (col. 5, lines 23-52); placing a second base unit (col. 5 lines 23-27) onto the earmold; and attaching the securing mechanism (50, 52, 110, 112). Voroba does not teach the securing mechanism capable of being released by a user without the use of a separate tool or instrument. Schroder teaches an alternate rotational connection means (col. 2 line 59 through col. 3 line 2) for securing two hearing aid modules together and making it easier to disconnect the two housings. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the rotational connection means in the invention of Voroba as taught by Schroder to make the two housings easier to separate. However, it is known in the art to be able to replace the earmold portion within the life expectancy of the aid if the structure becomes compromised, i.e. brittle and torn, and improve comfort and hygienic concerns for the user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to change the earmold of Voroba in view of Schroder within the life expectancy of the aid for improved comfort and hygienic concerns.

7. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Diethelm** (U.S. Patent No. 3,852,540), in view of **Voroba** (U.S. Patent No. 4,870,688), and in view of **Baum** (U.S. Patent No. 2,487,038), and in further view of **Knudsen** (U.S. Patent No. 2,246,737)

Regarding claims 20 and 21, Diethelm teaches a base unit (2), an earmold (1, 3) comprising a battery (7, 8) and receiver (5), and a retention mechanism (col. 3 lines 13-34). Diethelm does not teach the type of material used for the earmold; however, it is known in the art, as evidenced by Voroba (30), to use soft, malleable, compliant material for the earmold to facilitate comfort to the user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the shell of Diethelm from a soft, malleable, compliant material to facilitate comfort to the user. Furthermore, the combination of Diethelm and Voroba does not teach the earmold having a flexible, mushroom shaped earmold tip. However, it is known in the art, as evidence by Baum (figs. 1-5), for an earmold tip to have horizontal flanges (Knudsen; 12) for tightly sealing the auditory canal to the outside, providing comfort to the user, and for simulating a mushroom shaped tip. Therefore, it would have been obvious to one of ordinary skill in the art to include the flange(s) of Knudsen onto the earmold (Diethelm; 1, 3) of the combination of Diethelm and Voroba for tightly sealing the auditory canal to the outside and providing comfort to the user.

8. Claims 25, 27-39, 41-42, and 58-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Diethelm** (U.S. Patent No. 3,852,540), in view of **Baum** (U.S. Patent No. 2,487,038).

Regarding claims 25 and 27, Diethelm teaches an earmold tip (Diethelm (1, 3) comprising a vibration isolation portion (Diethelm, 1) adapted to attachment with in a hearing aid having a receiver (Diethelm, 5). Diethelm does not teach the earmold having a flexible, mushroom shaped earmold tip. However, it is known in the art, as evidence by Baum (figs. 1-5), for an earmold tip to have horizontal flanges (Baum; 11) for tightly sealing the auditory canal to the outside, providing comfort to the user, and for simulating a mushroom shaped tip. Therefore, it would have been obvious to one of ordinary skill in the art to include the flange(s) onto the earmold tip (Diethelm; 1, 3) for tightly sealing the auditory canal to the outside and providing comfort to the user.

Regarding claims 28, 30, and 38, the combination of Diethelm and Baum teaches the earmold tip comprising a sound bore (Diethelm; 6, 6a, 22, 23).

Regarding claim 29, the combination of Diethelm and Baum does not teach a spring surrounding the sound bore. However, the examiner takes official notice that it is known in the art to insert springs into earmold tips to increase stiffness and control navigation of the tip along the ear canal. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a spring in the invention of Diethelm and Baum to increase stiffness and control navigation.

Regarding claim 31, the combination of Diethelm and Baum teaches the vibration isolation (Diethelm, 1) mechanically decouples the receiver (Diethelm, 5) from a hearing aid base unit to isolate the mechanical vibrations of the receiver from the base unit (Diethelm, 2).

Regarding claim 32, the combination of Diethelm and Baum teaches the hearing aid includes the base unit (Diethelm, 2) in which is mounted a microphone (Diethelm, 15).

Regarding claim 33, the combination of Diethelm and Baum teaches the hearing aid includes a base unit (Diethelm, 2) in which is mounted a microphone (Diethelm, 15) and the vibration isolation (Diethelm, 1) comprises a nest in which the receiver sits to acoustically seal the receiver within the vibration isolation portion thereby acoustically isolating the base unit from the acoustical vibrations created by the receiver (Diethelm, 5).

Regarding claim 34, the combination of Diethelm and Baum teaches the vibration isolator portion (Diethelm, 1) partially covers the receiver (Diethelm, 5).

Regarding claim 35, the combination of Diethelm and Baum does not teach an adhesive wherein the adhesive secures and acoustically seals the receiver to “the earmold” (examiner believes that this should be *vibration isolation portion* and has presented a rejection based on this and the claim objection above). However, the examiner takes official notice that it is known to use some form of adhesion to secure and acoustically seal the receiver to a vibration isolation portion for the beneficially preventing the receiver from moving out of alignment due to normal ear movements, such as during talking, eating. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was to use adhesion to secure and seal the receiver to the earmold.

Regarding claims 36, 39, 41, and 63, refer to claims 25, 26, and 28.

Regarding claim 37, refer to claim 29.

Regarding claims 42, claims 25, 27, 34, 35, 36, former claim 40, 41 cover the limitations of these claims.

Regarding claims 58-60, see the rejection of claims 25 and 26.

Regarding claim 61, see the rejection of claims 28, 30, 38 as they relate to claims 58.

Regarding claim 62, see the rejection of claims 4, 6, 11, 16, 20-21 as they relate to claims 58.

Allowable Subject Matter

9. Claims 46, 48 and 50-54 are allowed.

Response to Arguments

The Applicant's arguments filed have been fully considered but they are not persuasive. Upon further review of the patents used in view of the applicant's arguments, the examiner contends that the rejections made are supported and applicable the present claims.

With respect to the applicant's first argument (page 13, 1st paragraph) pertaining to paragraphs 2 and 4-7 above, the examiner used primarily use Voroba, Diethelm, and Baum to satisfy the requirement that the earmold have a removable component (Voroba 99, 100, col. 7 lines 51-68, col. 10 lines 60-64; Diethelm 7), and a disposable compliant earmold (Voroba, 30).

With respect to the applicant's first argument (page 13, 2nd paragraph) pertaining to 112 rejections, they have been removed.

With respect to the applicant's first argument (page 14, 1st complete paragraph) pertaining to paragraph 8 above, the examiner satisfied the mushroom shaped tip portion being integral to a vibration isolation portion in the rejection with an official notice of which support can be found either the PTO-892 or PTO 1449 listing of references, such as Huntress, US Patent No. 4,055,233.

With respect to the applicant's first argument (page 14, 2nd paragraph) pertaining to paragraph 3 above, the examiner satisfied this rejection with the Yoest reference. The examiner contends that the potting material is inside the base unit once the ring 86 of base unit 70, 90 is engaged (col. 3 lines 62-67, col. 4 lines 14-21).

With respect to the applicant's first argument (page 15, 1st and 2nd complete paragraphs) pertaining to paragraph 8 above, the examiner has reviewed the Shennib reference; however, the applicant has not provided clarification as to which claims and how these claims are specifically at issue with the present application.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phylesha L Dabney whose telephone number is 703-306-5415. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, Fridays 8:30-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Curtis Kuntz can be reached on 703-305-4708. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-4700.

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 872-9314, for formal communications intended for entry and for informal or draft communications, please label "Proposed" or "Draft" when submitting an informal amendment.

(703) 306-0377, for customer service questions.

Hand-delivered responses should be brought to Crystal Park II, 2121 Crystal Drive, Arlington, VA, Sixth Floor (Receptionist).

January 22, 2004



PLD



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